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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,356

09/11/2003

Duran Yetkinler

SKEL-012

6769

24353 7590 01/09/2007
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EXAMINER

RAMANA, ANURADHA

ART UNIT

PAPER NUMBER

3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/661,356

Applicant(s)

YETKINLER ET AL.

Examiner

Anu Ramana

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-9,11,31-41 and 43-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-9,11,31-41 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 7, 11, 32 and 33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 33-40, 42-45 and 47 of copending Application No. 10/797,907.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the claims of the present application and the claims of the copending application is that the claims of the copending application include many more elements and are thus more specific. Thus the invention of the claims of copending application is in effect a "species" of the "generic" invention of the claims of the present application. It has been held that the generic invention is "anticipated" by the "species." See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the claims of the present application are anticipated by the

claims of the copending application, they are not patentably distinct from the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-2, 6-9, 11, 31-41 and 43-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 11 and 36, it is unclear what Applicants mean by "stops simultaneously with cessation of vibration." Applicants disclosure states at Page 5, lines 5-16 that simultaneously stops means that movement of cement continues for no more than 5 seconds, such as no more than 1 to about 3 seconds.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 6-9, 11, 31-34, 36-41 and 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) in view of Sproul (US 6,832,988).

Constantz et al. disclose a method of introducing calcium phosphate cement for orthopedic applications utilizing a cement delivery means such as a needle wherein the

needle is vibrated to enhance perfusion of cement (col. 25, lines 38-59, col. 27, lines 11-57, col. 28, lines 49-67 and col. 29, lines 1-67).

Constantz et al. clearly disclose that vibration can be utilized instead of application of pressure (underline emphasis added) to enhance cement infiltration or promote efficient infiltration (col. 27, lines 31-57). Thus, when vibration is stopped, infiltration would also be "simultaneously stopped" since the driving force for cement delivery would be removed.

Although Constantz et al. do not make an explicit reference to a vibratory element attached to the cement delivery means or needle such an element would be necessary in order to vibrate the cement delivery needle.

It is very well known in the art to vibrate an element such as a needle by placing the element in a holder of a vibratory element. To support this position, the Examiner directs Applicants' attention to Sproul who discloses an ultrasonic probe 91 placed in a connector or holder 94 in order to vibrate the probe by means of an ultrasonic pulse generator (Fig. 7 and col. 7, lines 37-43).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have attached the Constantz et al. needle to an ultrasonic generator by placing it in a holder, as taught by Sproul, for the purpose of vibrating the needle.

Regarding claim 6, Sproul teaches maceration and aspiration of soft tissue or marrow inside hard bone to create a void for receiving a reinforcement agent during vertebroplasty (col. 7, lines 15-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized maceration and aspiration to remove soft tissue or marrow from bone, as taught by Sproul, in the method of the combination of Constantz et al. and Sproul, to create a void for receiving a reinforcement agent during vertebroplasty.

Regarding claim 31, Constantz et al. disclose removal of marrow matter prior to introduction of calcium phosphate (col. 26, lines 43-48).

Regarding claim 39, Constantz et al. disclose that the amount of flowable calcium phosphate cement utilized depends on the nature of the vertebral body being treated (col. 27, lines 2-9).

Constantz et al. disclose all elements of the claimed invention except for the amount of cement being about 4 to 10 cubic centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized 4 to 10 cubic centimeters of cement, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 44-45, since vibration is being used instead of application of pressure, the applied pressure will be atmospheric or near atmospheric (approximately 14 psi).

Regarding claim 47, it is well known to prepare a calcium phosphate cement by combining a calcium and a phosphate source with a silicate setting fluid (see US 6,375,935).

Claims 1-2, 7-9, 11, 31-41 and 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) in view of Rabiner et al. (US 6,551,337).

Constantz et al. disclose all elements of the claimed invention except for the needle being vibrated by placing the needle in a holder of a vibratory element wherein the vibratory element is a pneumatic vibratory element. See previous discussion of Constantz et al.

Rabiner et al. teach attaching a probe 12 to be vibrated to an ultrasonic driver or vibratory element 14 via an ultrasonic coupling horn or "holder" 16 wherein the vibratory element can utilize a variety of methods such as pneumatic, piezoelectric etc. to produce ultrasonic vibration (Fig. 1 and col. 2, lines 46-65).

Accordingly, it would have been obvious to one of ordinary skill in the art to vibrate the Constantz et al. needle by attaching the needle to a pneumatic vibrator or "vibratory element" by means of a holder, as taught by Rabiner et al., since it was

known in the art to utilize a vibratory element such as a pneumatic vibratory element to vibrate a probe or needle-like member.

Regarding claim 31, Constantz et al. disclose removal of marrow matter prior to introduction of calcium phosphate (col. 26, lines 43-48).

Regarding claim 39, Constantz et al. disclose that the amount of flowable calcium phosphate cement utilized depends on the nature of the vertebral body being treated (col. 27, lines 2-9).

The combination of Constantz et al. and Rabiner et al. discloses all elements of the claimed invention except for the amount of cement being about 4 to 10 cubic centimeters. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized 4 to 10 cubic centimeters of cement, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Regarding claims 44-45, since vibration is being used instead of application of pressure, the applied pressure will be atmospheric or near atmospheric (approximately 14 psi).

Regarding claim 47, it is well known to prepare a calcium phosphate cement by combining a calcium and a phosphate source with a silicate setting fluid (see US 6,375,935).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 6,149,655) and Rabiner et al. (US 6,551,337) further in view of Sproul (US 6,832,988).

The combination of Constantz et al. and Rabiner et al. discloses all elements of the claimed invention except for aspirating marrow from cancellous bone.

Sproul teaches maceration and aspiration of soft tissue or marrow inside hard bone to create a void for receiving a reinforcement agent during vertebroplasty (col. 7, lines 15-52).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized maceration and aspiration to remove soft tissue or marrow from bone, as taught by Sproul, in the method of the combination of Constantz et al. and Rabiner et al., to create a void for receiving a reinforcement agent during vertebroplasty.

Response to Arguments

Applicants' arguments submitted under "REMARKS" in the response filed on October 18, 2006 have been fully considered but are not persuasive for the following reason.

Applicants' arguments are not directed to claim limitations. On pages 9 and 10, Applicants argue that "one of skill in the art would have interpreted the cement mixture of Constantz to be a thixotropic fluid. Accordingly, one would expect the calcium phosphate cement to act like a thixotropic fluid and become less viscous in response to vibration in a time dependent manner." How is Applicants' calcium phosphate cement different from Constantz's calcium phosphate cement? Further, if cessation of vibration stops penetration of cement into the cancellous bone due to unique properties of Applicants' bone cement, then these unique properties should be claimed.

As stated in the previous office action, regarding the limitation "stops simultaneously with cessation of vibration," it is noted that if vibration were the driving force instead of pressure for efficient cement infiltration, stopping vibration would remove the driving force and thereby simultaneously stop infiltration. Applicants' state that cement moves further for about 1 to about 3 seconds after vibration is stopped (page 5, lines 16). It is the Examiner's position that when vibration is stopped flow would stop in the method of the combination of Constantz et al. and Sproul to the same extent as Applicants' invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached on Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
January 4, 2007

Anu Ramana
1/4/07